MINUTES

SENATE HEALTH & WELFARE COMMITTEE

DATE:	Wednesday, February 08, 2017
TIME:	3:00 P.M.
PLACE:	Room WW54
MEMBERS PRESENT:	Chairman Heider, Vice Chairman Souza, Senators Martin, Lee, Harris, Anthon, Agenbroad, Foreman, and Jordan
ABSENT/ EXCUSED:	None
NOTE:	The sign-in sheet, testimonies and other related materials will be retained with the minutes in the committee's office until the end of the session and will then be located on file with the minutes in the Legislative Services Library.
CONVENED:	**Chairman Heider** called the meeting of the Senate Health and Welfare Committee (Committee) to order at 3:18 p.m.
APPROVAL OF MINUTES:	**Senator Agenbroad** moved to approve the Minutes of the January 26, 2017 meeting. **Senator Harris** seconded the motion. The motion carried by **voice vote.**
GUBERNATORIAL APPOINTMENT:	**Consideration of Gubernatorial Appointment of Beth Elroy to the Board of Environmental Quality. Vice Chairman Souza** moved to send the Gubernatorial Appointment of Beth Elroy to the Board of Environmental Quality to the floor with recommendation that she be confirmed by the Senate. **Senator Jordan** seconded the motion. The motion carried by **voice vote.**
GUBERNATORIAL APPOINTMENT:	**Consideration of Gubernatorial Appointment of Carol Mascarenas to the Board of Environmental Quality. Senator Harris** moved to send the Gubernatorial Appointment of Carol Mascarenas to the Board of Environmental Quality to the floor with recommendation that she be confirmed by the Senate. **Senator Martin** seconded the motion. The motion carried by **voice vote.**
PRESENTATION:	**Epidiolex Expanded Access Program. Dr. Christine Hahn,** State Epidemiologist with the Department of Health and Welfare (Department), introduced herself to the Committee. **Dr. Hahn** provided background information to the Committee on the clinical trial of Epidiolex, an experimental drug derived from cannabidiol (CBD). The Department was instructed by the Governor in 2015 to administer the clinical trial to provide Epidiolex to children with severe epilepsy. Epidiolex is not yet approved by the Federal Drug Administration (FDA) for use in the U.S. but it was available through an Expanded Access Program (Program). The medication is derived from the cannabis plant, but all the Tetrahydrocannabinol (THC) has been removed. CBD oil is administered as drops under the tongue. **Dr. Hahn** stated the Idaho Program was initially approved for 25 children, and this year approval was given to enroll an additional 15 children. The children must be Idaho residents aged 18 or under and must have severe epilepsy not controlled by medications. The clinical trials around the country have been promising enough that the drug may be approved within the next year.

Chairman Heider welcomed Dr. Robert Wechsler to the Committee and thanked him for his work with the children on this clinical trial. **Dr. Wechsler** introduced himself to the Committee as a researcher in many clinical trials and an investigator for GW Pharmaceuticals (GW) in other trials of Epidiolex. GW recommended Dr. Wechsler as a researcher for the Idaho Program because of his experience. The Idaho Program was originally approved for 25 places, and there was a question whether that number would be sufficient to accommodate the need. The Idaho Program requires children to be referred by a pediatric neurologist who has reviewed the child's chart and can attest that all reasonable appropriate therapies have otherwise been exhausted.

Dr. Wechsler informed the Committee out of the original 25 places, one child could not stay in the Idaho Program because he could not tolerate having blood draws. The first 24 patients are all still involved, and **Dr. Wechsler** said he presented the data on those patients to the American Epilepsy Society meeting in abstract and poster form in December 2016. Per FDA guidance and GW policies, the clinical trial is run as an "open label" research study, meaning there is no placebo and all participants receive the actual medication. With an open label research study, there is not much motivation for participants to exit the program, even if they are not seeing a real benefit. About two-thirds of participants receive a genuine benefit. Only about 20 percent of participants have experienced a significant reduction in the number of seizures, but he has heard from some families that the intensity and duration of their children's seizures has decreased. **Dr. Wechsler** mentioned he takes these reports with a grain of salt because there is no empirical evidence to support the claims.

Dr. Wechsler advised there were a few cases on the waiting list last year, so he approached GW about expanding the Program. Idaho's Program was one of the few in the U.S. that was allowed to expand to add 15 places. The Program has done well in meeting the need, and there is not a big waiting list at this time. By being thoughtful about the criteria to include participants at the outset of the trial, the demand has tapered off quite a bit. For example, **Dr. Wechsler** said he was contacted in late 2016 by the neurologist of the child who could not tolerate the blood draws. The neurologist asked if the child could be readmitted to the Program. **Dr. Wechsler** informed the neurologist he hated to lose a second place if it turned out the child still could not tolerate the blood draws, and the parents assured him the child would be fine with blood draws at this time. At this time there are 38 participants in the Program with one place left, and they intend to add this child for the last place.

Dr. Wechsler stated some patients have benefited quite a bit from the use of Epidiolex, but he believes there is a healthy dose of wishful thinking mixed in for others. Overall, the successes are on par with other clinical trials of the drug. There is a strong likelihood the drug will be approved once it is submitted to the FDA. The approval process takes several months, but it is very possible the drug will be available commercially in early 2018. At that point, the Program will no longer be necessary.

Chairman Heider asked if prolonged use of the drug will continue to make an improvement in the patient's status. **Dr. Wechsler** answered his gut feeling is that this product will be on par with any other product approved for epilepsy. It will not be dramatically better than other drugs, but there will be individuals for whom it is better than anything else they tried. However, that is true of many of the patients he treats with a variety of drugs. His best guess is that some will have sustained success, and some will have success for a while and the benefits will taper off. Every time a new drug comes along, there are a few people for whom it turns out to be the miracle they were waiting for. Others do well only for a while, and these are often the patients who end up in future clinical trials of other drugs.

Chairman Heider inquired how long it will be until the FDA approves the drug and it is available to every Idaho child with this condition. **Dr. Wechsler** responded GW has fast-track status. GW's data is presently being looked at by its statisticians, and he believes GW will submit for FDA approval in the first half of 2017. It will likely take eight to twelve months for FDA approval after submission.

Senator Jordan asked if Dr. Wechsler noticed any unusual or adverse effects from the drug during the study. **Dr. Wechsler** responded adverse effects are the main reason to conduct this type of study. The benefit of this kind of study is to collect information on safety and tolerability. The tolerability of the drug has been surprisingly good. The most common side effect encountered has been sedation or sleepiness, particularly in patients who are taking one or more other epilepsy medications. There is a significant interaction between CBD and two other commonly-used epilepsy drugs that causes the sedation side effect. **Dr. Wechsler** said he primarily deals with adult patients and it is important for the child's pediatric neurologist to stay involved. When he sees side effects, he sends the child back to the referring provider to adjust the child's medications as appropriate. Out of the 24 initial patients, seven had significant drowsiness as a consequence of adding CBD oil. Most of the seven were taking both of the other two common medications, and the side effect was reduced with the reduction or elimination of one or both of those two drugs.

Senator Harris asked what is the anticipated market cost of the drug after it is approved. **Dr. Wechsler** replied he has no idea. However, the data shows Epidiolex does not achieve dramatically better results than any other approved epilepsy drug. He feels GW will be obliged to price the product competitively with every other approved drug. There has been excitement surrounding this topic, but that must be tempered by competition from artisanal dispensaries in the 22 states that have approved medical or recreational marijuana. He knows some of the people leading this project at GW and they are very smart, good people. He does not think they would price things ridiculously high.

Senator Souza commented this is an important topic and there was a lot of emotion surrounding it at the Legislature last year. She asked if Dr. Wechsler knows of Idaho children with severe epilepsy who might benefit from the drug but who did not qualify for the clinical trial because they didn't meet the criteria. **Dr. Wechsler** answered the main criteria for the Program was that at least four conventional approved therapies for the patient's epilepsy type must have been tried and failed, including one combination of two medications. The criteria were set loosely, and while there are many children who would technically meet the criteria, their referring neurologists recognized there were more things to be tried first. When a product is FDA approved and shown to be effective and safe, it gets broader use than in the clinical trials because the trials carry an element of risk and it is unknown whether there will be long-term health risks. Children are not included in clinical trials unless all other reasonable options have been exhausted. **Dr. Wechsler** commented he thinks the demand will be fairly significant when the drug is approved and it will have a successful launch. He thinks there might a little bit of disappointment six to 12 months after approval because he does not think the drug will live up to the hype. Sometimes there is hesitancy to prescribe a new drug right after it is approved, but he does not think that will be the case with this particular drug due to the political environment around it.

Senator Souza inquired whether Epidiolex is currently available in other countries. **Dr. Wechsler** answered it is not currently available for epilepsy in other countries.

Senator Souza further inquired whether the drug will likely be prescribed for adults for reasons other than epilepsy. **Dr. Wechlser** responded it is hard to predict what prescribers will do, and he suspects there will be some effort to prescribe it for all kinds of things, whether it has been shown to work for those things or not. Once GW has approval, he thinks the drug will be tested in other areas to see if it has any benefit. He thinks it will definitely have a role for adults with epilepsy. The FDA approval sought is for two different syndromes: Lennox-Gastaut Syndrome (LGS) and Gervais Syndrome (GS). There is a misperception in the medical community that these are only childhood diseases. In the clinical trial of another epilepsy drug, 80 percent of participants with LGS were children. Unfortunately, children with LGS do not suddenly become normal at age 18; they become adults with the same condition. Many patients with LGS live to their 50's and 60's; he has a 70-year-old patient with LGS in a Boise group home. Of all patients with LGS, the adults dramatically outnumber the children, but there is more complacency about the diagnosis and the seizures in adult patients. **Dr. Wechsler** explained he has participated in a number of LGS studies, and most participants were adults with LGS. He feels Epidiolex will have a role in the care of adult patients. Many of these adults end up in State facilities or group homes, and they will potentially benefit greatly.

Senator Lee commented there was significant debate about this issue in 2016 and asked if there is something different about this particular drug versus other CBD oil that can be purchased online or in other states. **Dr. Wechsler** answered the biggest difference is that Epidiolex will have a regulated content of CBD oil. The problem with artisanal preparations is the content is not regulated. As an example, the FDA pulled random samples of 18 products from six different manufacturers available on the Internet. Sixteen of the 18 products had zero percent CBD. The other two had less than two percent CBD. Epidiolex contains 100 milligrams (mg) of CBD per milliliter (ml). The "Cadillac" version of CBD oil is called "Charlotte's Web" and has about 50 mg of CBD per ml, but it is not regulated by any kind of authority. Dr. Wechsler has a patient who buys Charlotte's Web online from Colorado, and the company selling it has told the patient the correct dose is 7 ml, or about 350 mg. In the Epidiolex studies, doses are commonly as high as 25 mg per kilogram of body weight. For an average size person, the dose might be as high as 2,000 mg. Another patient who is buying a highly purified CBD oil received instructions to place three drops under her tongue for one week, then increase to nine drops under the tongue. It is not chemically possible to have enough CBD in nine drops of oil to get a meaningful dose. It is unfortunate that people have such strong belief in CBD oil that they stop their mainline therapies. His colleagues in the pediatric epilepsy world in Colorado reported the number of children showing up in emergency rooms with seizure emergencies has dramatically risen since the marijuana dispensaries opened. Families are putting their children on CBD oil and taking them off their medications without physician approval.

S 1037

Relating to Dentists. Susan Miller, Executive Director of the Idaho State Board of Dentistry (Board), introduced herself to the Committee to present **S 1037**. The bill revises Idaho Code § 54-920 and addresses three issues.

Ms. Miller informed the Committee that licensees who choose retirement status currently have no option to return to active status other than to apply as a first applicant. The Board explains this issue to licensees in their renewal materials, but some don't read the fine print. Some licensees inadvertently made a poor choice and wanted to reactivate the licenses later, but the statute expressly prohibits the Board from converting a retirement license to an active status license.

Ms. Miller explained the current definition of active status allows licensees to absent their practice for up to two years for only the reasons specified in the statute. There are other reasons a licensee may wish to absent the practice, and in some cases, it may be for longer than a two-year period.

Ms. Miller said the third issue has to do with converting an inactive status license to active status. The current statute requires evidence of 1,000 hours of clinical practice within the two years immediately prior to making the request to activate a license. Requiring continuing education instead of clinical practice hours would be consistent with the requirement for an active status practitioner who may or may not actually be practicing.

Ms. Miller reviewed the proposed changes to the statute. The bill would:

- eliminate the retirement status fee;
- revise the definition of active status to allow absence from practice for any reason;
- eliminate the retirement status definition;
- delete the requirement for license applicants to show intent to engage in practice within two years;
- allow licensees to go on inactive status for any reason;
- remove the clinical practice requirement for converting a license from inactive to active status and replace it with a continuing education requirement; and
- revise the statute to eliminate conflicting language and clarify what must be done to qualify for an active status license.

Ms. Miller reported the Board has heard no opposition to the bill. The Idaho State Dental Association and the Idaho Dental Hygiene Association are both in support of the legislation. **Ms. Miller** stated the Board's public member, Tina Wilson, and Board counsel Michael Kane are both present and available to answer questions.

Senator Lee asked if a licensee goes on inactive status for ten years and wishes to reactivate, would the licensee be required to complete the same hours of continuing education as if the licensee had been on active status during that period. **Ms. Miller** answered that is correct.

Senator Foreman asked if there is a way to ensure a licensee is not required to complete outdated or unavailable courses. **Ms. Miller** replied the Board rules do not specify particular areas of continuing education. The courses must be oral health or health related. **Senator Foreman** commented his concern is that the courses are current and relevant rather than going back to complete courses that might have been required in the past and are now outdated. **Ms. Miller** responded if a licensee had been inactive for ten years, it is true the licensee could have completed the education nine years ago and it would not be current. That issue was not contemplated in this legislation, but if the Board begins to see this type of problem, it will be addressed in future legislation.

Senator Martin stated he perceives the intention is to make it easier for dentists to reinstate licenses but asked why the language was stricken to remove the Board's discretion. **Ms. Miller** answered the Board felt there was an inconsistency between the language setting forth the requirements and the section pertaining to Board discretion.

TESTIMONY:

Elizabeth Criner introduced herself on behalf of the Idaho State Dental Association (ISDA). **Ms. Criner** stated the ISDA supports the bill and appreciated the opportunity to work with the Board on the legislation.

Senator Martin asked Ms. Criner her opinion of the effect of the bill. **Ms. Criner** replied the bill provides an opportunity for dentists who decide on early retirement to maintain licensure and have an opportunity to return to practice. The bill provides flexibility and appropriate oversight, and education requirements are a good way to move forward with that option.

MOTION: **Vice Chairman Souza** moved to send **S 1037** to the floor with a **do pass** recommendation. **Senator Anthon** seconded the motion. The motion carried by **voice vote.**

S 1038 **Relating to Dentists. Michael Kane** introduced himself to the Committee as General Counsel for the Board. **Mr. Kane** explained **S 1038** would give the Board specific authority to engage in emergency proceedings when there is an immediate danger to public health. **Mr. Kane** informed the Committee about a situation involving a dentist who allowed untrained dental assistants to administer intravenous anesthetics, write prescriptions for controlled substances on pre-signed prescription pads, and sedate a patient and drill and fill a tooth. When the Board learned of this situation, it began an emergency proceeding and asked the Attorney General's (AG's) Office for assistance. The day of the proceeding, the AG's Office advised the Board it did not have authority to conduct the emergency proceeding. **Mr. Kane** pointed out the Administrative Procedures Act (APA) provision that allows regulatory boards to conduct emergency proceedings, and the AG's Office said that section of the APA was inapplicable to the Board's emergency authority.

Mr. Kane said the AG's Office provided a lengthy opinion in support of its position (see Attachment 1). The legislation would authorize the Board to conduct an emergency proceeding in the same manner as the other medical boards and the Board of Veterinary Medicine. The proposed language is identical to that authorized by the Legislature for the Board of Veterinary Medicine. Although the Board is unlikely to encounter a similar situation for many years, it will allow the Board to issue a sort of temporary restraining order to hold things in place until a full hearing on the merits can be conducted.

Mr. Kane stated the fiscal note has been revised in accordance with Senate rules and there is no impact to the General Fund.

Senator Lee asked if this issue could be addressed across all boards and further inquired if there were any other sanctions that could be imposed on the dentist to stop the behavior. **Mr. Kane** responded this was the only sanction available to the Board. There are criminal sanctions available but the Board has no jurisdiction, and criminal proceedings can go on for a year or longer.

Senator Anthon said the AG's Office is not always correct, and he inquired what is authorized in subsection 6(b) of the bill that could not be done in subsection 6(a). **Mr. Kane** replied he was a former Deputy Attorney General and occasionally wrote opinions, and they are just opinions. In this situation, the AG's Office was also counseling the Board as to what they could and couldn't do. The Board's own attorney was telling the Board it couldn't conduct the emergency proceeding. Subsection 6(a) describes the Board's standard process of investigation, filing a complaint, pretrial fillings, and a hearing. This process can go on for one year or more, even to come to a stipulated resolution. It is very rare to try a case involving a dentist; 99 percent of the time the Board reaches an agreed-upon resolution such as a reprimand up to and including revocation of a license. The bill allows the Board to act on a temporary, emergency basis and conduct a quick hearing where the hearing officer will determine whether there is potential risk of immediate danger to the public health. The licensee can do almost anything to continue practicing but the Board can dictate certain

conditions of practice while the matter is fully adjudicated. Some cases go all the way to the Supreme Court and the regular process can be lengthy.

Senator Anthon stated he is still confused and reviewed the section of the Board's enabling legislation that says proceedings will be conducted in accordance with the APA, which specifically authorizes emergency proceedings. In his opinion, the bill adds language which further narrows the conditions under which an emergency proceeding can be conducted. **Mr. Kane** replied he agrees with the interpretation, and the Board has no desire to speed up the process for handling typical violations. The Board is stuck with the AG's interpretation of the APA.

Senator Anthon asked why there is no reference to judicial review in subsection 6(b) when subsection 6(a) provides for judicial review of actions taken under that subsection. **Mr. Kane** responded judicial review would apply under the APA. An emergency proceeding would allow the Board to tell a licensee to stop certain actions, and the Board would then conduct a full proceeding under subsection 6(a). As a matter of law under the APA, the licensee is always entitled to judicial review any time a licensee's substantive right is affected. There could be judicial review even while the slower proceeding is underway.

MOTION: **Senator Martin** moved to send **S 1038** to the floor with a **do pass** recommendation. **Senator Jordan** seconded the motion.

DISCUSSION: **Senator Anthon** commented Mr. Kane has done an excellent job and the Board has been restricted. The bill is not very well drafted and is unnecessary. **Senator Anthon** said he will not support the motion.

Senator Foreman stated he agrees with Senator Anthon. Mr. Kane has done a good job but the bill is a complete redundancy, and the Board already has the authority to do what it needs to do. **Senator Foreman** said he does not like to see new laws that repeat existing law.

Senator Lee mentioned she agrees letters of advice should not direct legislation. However, there is a precedent that has hampered the Board's ability to act on an egregious situation. The substance and spirit is to allow the Board to immediately sanction a licensee when necessary. It may not be perfect, but she will support the motion in the interest of public safety.

SUBSTITUTE MOTION 1: **Vice Chairman Souza** said she agrees with Senator Anthon's concern about the lack of judicial review in the new language. **Vice Chairman Souza** made a substitute motion that **S 1038** be held subject to the call of the Chair. **Senator Anthon** seconded the motion.

SUBSTITUTE MOTION 2: **Senator Lee** made an alternate substitute motion to send **S 1038** to the 14th Order for possible amendment. **Senator Jordan** seconded the motion.

Chairman Heider called for a vote on substitute motion 2 to send **S 1038** to the 14th Order for possible amendment. The motion failed by **voice vote.**

Senator Jordan stated she appreciates the intent of the substitute motion but her primary concern is the Board would be left without an option to fix the problem for quite a while. Other Board statutes address similar situations in the same way to protect public safety. **Chairman Heider** commented current law remains in place if there is no action taken. **Senator Jordan** said the existing statute does not accommodate this particular circumstance. **Chairman Heider** mentioned the current statute includes hearing provisions in subsection 6.

Senator Foreman said existing law does protect the public and the Committee should stand on existing law. He does not support the substitute motion.

Senator Lee mentioned there is precedent in other board statutes. The fact other boards have this language creates a vulnerability for the actions the Board was trying to take. The new language would give the Board the contemplated authority. Holding the bill in committee would create a lack of parity with other boards and might result in revisiting the issue next year.

Chairman Heider called for a roll call vote on substitute motion 1 to hold **S 1038** subject to the call of the Chair. **Vice Chairman Souza, Senators Harris and Anthon, and Chairman Heider** voted aye. **Senators Martin, Lee, Foreman, and Jordan** voted nay. The substitute motion failed on a tie vote.

Chairman Heider called for discussion on the original motion.

Vice Chairman Souza said the bill is well intended and her only concern is the lack of judicial review in the added language. Although Mr. Kane assured that would be covered and she understands the concerns about duplicating language, she will support the original motion.

SUBSTITUTE MOTION 3:

Senator Anthon commented the legislation would make it harder for the Board to exercise its emergency powers and asked if the Chair would entertain another substitute motion to send the bill to the amending order. **Senator Anthon** moved to send **R 1038** to the 14th Order for possible amendment. **Senator Harris** seconded the motion.

Senator Anthon said he was originally in favor of holding the bill but he understands the wishes of the Committee and thinks the next best option is the 14th Order.

Chairman Heider called for a roll call vote on substitute motion 3 to send **S 1038** to the 14th Order for possible amendment. **Vice Chairman Souza, Senators Lee, Harris, Anthon, Jordan, and Chairman Heider** voted aye. **Senators Martin and Foreman** voted nay. The substitute motion carried. No vote was taken on the original motion.

ADJOURNED:

There being no further business at this time, **Chairman Heider** adjourned the meeting at 4:40 p.m.

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Senator Heider
Chair

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Jeanne Jackson-Heim
Secretary